

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, AND MITSUI SUGAR
CO., LTD,**

Plaintiffs

v.

**HEC PHARM CO., LTD., HEC PHARM
GROUP, AND HEC PHARM USA, INC.,**

Defendants.

Civil Action No.: 15-1647 (CCC)

MEMORANDUM OPINION

FALK, U.S.M.J.

Before the Court is Plaintiffs' motion to stay this case pending ongoing litigation between the same parties in the United States District Court for the District of Delaware. [ECF No. 10.] The motion is opposed. Full briefing has been submitted, including Court-authorized sur-replies. No argument is necessary. Fed. R. Civ. P. 78(b). For the reasons stated below, Plaintiffs' motion is **granted**. This case is stayed and administratively terminated.

BACKGROUND

This is a Hatch-Waxman patent infringement case.¹ Plaintiffs allege infringement of U.S. Patent No. 5,604,229 (the “‘229 patent”), which covers the active ingredient in Gilenya®, Plaintiffs’ multiple sclerosis drug. This action, commenced on March 5, 2015, is the second-filed infringement suit by Plaintiffs against the same Defendants alleging infringement of the ‘229 patent.

On February 11, 2015, Plaintiffs commenced suit against Defendants in the United States District Court for the District of Delaware (the “first action”) alleging infringement of the ‘229 patent. That filing commenced a statutory 30-month stay of regulatory approval of a generic drug while the patent litigation is pending. See 21 U.S.C. § 355(j)(5)(B)(iii).

On March 2, 2015, Defendants filed a motion to dismiss the Delaware case for lack of personal jurisdiction, or in the alternative, to transfer the case to the District of New Jersey. In response, three days later, on March 5, 2015, Plaintiffs commenced this case in New Jersey (the “second action”) “to protect Plaintiffs’ rights should the first case be dismissed for lack of personal jurisdiction.” (Pls.’ Br. 3.) Plaintiffs’ contention is that it was necessary to file the second action in this court—informally referred to in the case law as a “protective suit”—because it is unclear whether the 30-month regulatory stay is

¹ Plaintiffs are: Novartis AG; Novartis Pharmaceuticals Corporation; Mitsubishi Tanabe Pharma Corporation; and Mitsui Sugar Co., Ltd. Defendants are: HEC Pharm Co., Ltd.; HEC Pharm Group; and HEC Pharm USA, Inc.

available if a suit is dismissed for lack of personal jurisdiction. (Id.) Thus, “out of an abundance of caution, Plaintiffs filed suits in Delaware, its preferred forum, and New Jersey.” (Id.)

On May 11, 2015, the Honorable Leonard P. Stark, U.S.D.J., denied Defendants’ motion to dismiss for lack of personal jurisdiction and/or to transfer to New Jersey without prejudice to “renew after the Federal Circuit Court of Appeals issues its decision in the pending interlocutory appeals that will likely address similar if not identical matters as presented by Defendants’ motion.” Novartis AG et al v. HEC Pharm Group et al., No. 15-151 (LPS) (D. Del.); Oral Order dated May 11, 2015, D. Del. CM/ECF No. 27.² Judge Stark also directed the parties to participate in a Rule 26(f) conference and propose scheduling order dates. Id., D. Del. CM/ECF No. 28.

On May 22, 2015, Plaintiffs filed the present motion to stay this case. Plaintiffs’ position is that jurisdiction has been resolved in Delaware and that the litigation is proceeding there. Since Delaware is Plaintiffs’ chosen forum, and because a Plaintiffs’ choice of forum is generally entitled to deference, Plaintiffs request that this second-filed action be stayed in favor of the first-filed Delaware suit. Plaintiffs have not sought

² Defendants’ motion to dismiss was apparently premised on the Supreme Court’s Opinion in Daimler AG v. Bauman, 134 S. Ct. 746 (2014). The Federal Circuit has certified interlocutory appeal of decisions regarding personal jurisdiction in Hatch-Waxman patent litigation in two proceedings unrelated to this case: Accordia Therapeutics Inc. v. Mylan Pharm. Inc., C.A. No. 15-124 (Fed. Cir. Mar. 17, 2015) and AstraZeneca AB v. Mylan Pharm. Inc., C.A. No. 15-117 (Fed. Cir. Mar. 17, 2015). (See Pls.’ Br. 4 n.6.)

dismissal of this action, it appears, as security against jurisdiction later being revisited in Delaware.

Defendants have opposed the motion to stay. They contend that Plaintiffs should not be entitled to rely on the first-filed rule and that the case should proceed in this district because there is no dispute over personal jurisdiction.

ANALYSIS

A stay of this case is appropriate for a multitude of reasons which are listed below.

1. It is plainly contrary to judicial economy, time, and energy for the same parties to litigate the same patent in two different district courts before two different District Judges. The parties are litigating over a patent, for which national uniformity is vital, and decisions relating to that patent should be made, when possible, by one District Judge. Defendants have already sought to dismiss the Delaware action or to have it transferred to New Jersey. That motion was denied. Defendants obviously disagree with that decision and intend to seek reconsideration and/or further review. Still, the Delaware Court declined to transfer the case and has not stayed its proceedings. The case therefore is proceeding in Delaware. It would make no sense, practically or legally, to have it simultaneously proceed in New Jersey.

2. Plaintiffs first filed their infringement action in Delaware. The general rule—referred to as the “first-filed rule”—is that it is “a well-established policy of the federal courts that in all cases of concurrent jurisdiction, the court which first has

possession of the subject matter must decide it.” Chavez v. Dole Food, Co., Inc., — F.3d —, 2015 WL 4732386, at *1 (3d Cir. Aug. 11, 2015). Here, that court would be the District of Delaware.

3. Defendants’ primary argument opposing a stay is that, under Third Circuit law, it is “improper” to apply the first-filed rule to filers of “protective suits” in ANDA cases.³ The argument is heavily premised on the notion that the first-filed rule does not apply when a plaintiff files both the “first” and “second” suits at issue.

For one thing, Defendants cite no binding authority in support of their position, instead citing non-binding, unpublished, district-level authority.⁴ While some of those district-level cases cite to Third Circuit authority, e.g., Walton v. Eaton Corp., 563 F.3d 66, 71 (3d Cir. 1977), the Third Circuit was not addressing the first-filed rule within the unique context of ANDA litigation, something generally within the purview of the

³ The parties dispute whether Federal Circuit or Third Circuit law is controlling on application of the first-filed rule. Defendants advocate for Third Circuit law because they appear to believe that, in this Circuit, the first-filed rule is nullified when the same party commenced both the first and second lawsuits. (Defs.’ Br. 8-11.) In the Undersigned’s view, for purposes of this motion, it is a dispute without functional difference, because as is explained in paragraph 3, the Third Circuit has recently rejected the foundation of Defendants’ argument. Thus, even accepting Defendants’ argument that Third Circuit law controls, the result is that a stay is nevertheless appropriate.

⁴ A number of these cases do not apply the first-filed rule because jurisdiction in the first filed action was unsettled. See, e.g., Adams Respiratory Therapeutics, Inc. v. Pharm. Holdings Corp., 2006 WL 7077359 (E.D. Pa. Nov. 2, 2006). While Defendants may contend that jurisdiction is not conclusively settled in Delaware and take issue with the manner in which it was decided, the fact is, at this point in time, the matter is proceeding in Delaware.

Federal Circuit.⁵ Moreover, the cases Defendants cite are balanced by district-level authority from in and outside this District that suggests filing protective suits in ANDA cases is permissible and somewhat common practice. See, e.g., Cellegene Corp. v. Abrika Pharms. Inc., 2007 WL 1456156, at *4 (D.N.J. May 17, 2007); Pfizer Inc. v. Sandoz, Inc., 2010 U.S. Dist. LEXIS 4527, at *3 (D. Del. Jan. 20, 2010); Pfizer, Inc. v. Mylan, Inc., 2009 WL 10270101, at *1 (N.D. W. Va. Nov. 20, 2009) (noting that patent holder plaintiffs in Hatch-Waxman Act cases often “file protective ANDA suits in multiple jurisdictions as a hedge against the risk of dismissal for want of jurisdiction”).

Putting that aside, the foundation of Defendants’ argument—that the first-filed rule does not apply because Plaintiffs filed both the Delaware action and this case—was recently addressed by the Third Circuit in a published opinion:

The Appellants also argue that the first-filed rule does not apply because they filed both the Louisiana and Delaware actions themselves. It is true that most first filed issues arise where a plaintiff files in one district and then the defendant

⁵ For example, Walton is an employment case in which the plaintiff, after retaining substitute counsel and determining she was dissatisfied with her original pleading, filed a second lawsuit instead of seeking leave to amend her first complaint. Id. at 70. In doing so, the Third Circuit addressed, among multiple other things, whether the plaintiff was entitled to a jury trial on allegations in the second complaint when she waived the right in connection with the same allegations in the first action. Id. at 71. Refusing to allow the plaintiff to “use incorrect procedure [to] expand the procedural rights” she would have “otherwise enjoyed,” the Third Circuit found the right to a jury trial was waived for any matter asserted in the first action. Id. at 72, 74.

Walton does not materially bear on this patent case. The Undersigned disagrees with any district-level authority that suggests that Walton directly or indirectly refutes the somewhat common practice of filing protective suits in Hatch-Waxman litigation.

counter-sues in another [T]here is no authority, however, which holds that the first filed rule only applies in cases where the filings are initiated by different parties. For the rule to apply, all that is necessary is for the later filed action to involve the same parties and issues that are already before another federal court. **It does not matter that the cases were commenced by the same party Further, the principal reason for the first filed rule is avoidance of duplicative litigation, so it cannot matter whether the same party brought both suits—what matters is whether the second suit is duplicative of the first.**

Chavez, — F.3d —, 2015 WL 4732386, at *6 (emphasis added).

4. Defendants fail to establish any prejudice that would result from a stay of this case, at least for some time while matters proceed in Delaware. Defendants essentially contend that a stay would reward “judge shopping” and “force [them] from their proper jurisdiction, New Jersey.” (Defs.’ Br. 15.) Neither of these things are true. The record is devoid of any basis to allege “judge shopping.” What the record does show is that Plaintiffs want to ensure there is some forum to protect their statutory right to a Hatch-Waxman stay if their preferred forum is ultimately unavailable. And, while Defendants may contend their “proper jurisdiction” is New Jersey, the reality is Defendants are subject to suit in any forum in which they are subject to personal jurisdiction. At the present moment, Delaware is just as proper as New Jersey. Finally, if it is determined later that Defendants are not subject to jurisdiction in Delaware, there still would not be any prejudice. Any discovery that occurred in that case would presumably be equally applicable if the suit were to ever proceed in this District. In truth, the

“prejudice” that Defendants claim is being forced to *proceed in Delaware*, which is a decision that the Delaware court has made and this Court will not undermine.⁶

5. Even if Defendants were correct and the first-filed rule was given absolutely no consideration, the Court would nevertheless find that a stay is appropriate pursuant to its discretionary authority to control and manage cases on its docket, including to stay a case. See, e.g., Landis v. North Am. Co., 299 U.S. 248, 254 (1936); In re Fine Paper Antitrust Litig., 685 F.2d 810, 817 (3d Cir. 1982). Indeed, “[d]istrict courts possess inherent discretion to stay whenever the interests of justice mandate such action.” Akishev v. Kapustin, 23 F. Supp. 3d 440, 445 (D.N.J. 2014). As already stated, a stay would not prejudice Defendants and would favor judicial economy. Plaintiffs would also be prejudiced if forced to proceed in New Jersey because they would be litigating the same issues on parallel tracks risking inconsistent determinations. In short, the Ezra court persuasively stated why a stay here is necessary:

The risks inherent in Hatch-Waxman cases, the need for uniform application of patent law, and the goal of avoiding

⁶ Of note, Plaintiffs also filed a related Hatch-Waxman infringement action involving the same group of Plaintiffs, same patent, and same product against a different defendant in the United States District Court for the Eastern District of Arkansas. See Novartis AG, et al. v. Ezra Ventures, LLC, 15-95 (KGB); submitted as supplemental authority at ECF No. 31. The Ezra case is effectively identical to this one—i.e., Plaintiffs sued Ezra first in Delaware; Ezra filed a motion to dismiss for lack of personal jurisdiction; the Delaware court denied Ezra’s motion to dismiss without prejudice pending resolution of the Federal Circuit appeals; and Novartis moved to stay the second filed action in Arkansas. See Slip. Op. 2-3. The District Judge in Arkansas granted Novartis’s motion to stay relying on the first-filed rule and the inherent authority to stay pending litigation. Id.

duplicative litigation persuade this Court that maintaining the parties' action here in this Court would result in hardship and inequity to plaintiffs and waste judicial resources. These interests outweigh any potential prejudice to Ezra caused by a stay. Accordingly, for these reasons, the Court grants plaintiffs' motion to stay and hereby stays this action pending further resolution of jurisdictional issues, if any, in the District of Delaware.

Slip Op. at 8.

The alternative to a stay of this case is to have two different courts and two different District Judges simultaneously address the same patent and claims. That is the definition of duplication and a textbook example of waste of judicial resources. Even completely ignoring the first-filed rule, a stay is appropriate.

CONCLUSION

For the reasons stated above, Plaintiffs' motion to stay this case [ECF No. 10] is **GRANTED**. The case will be administratively terminated.

The parties are directed to apprise the Court in writing within 2 days of any further determinations relating to jurisdictional issues in the District of Delaware. Additionally, the parties are directed to provide this Court with periodic written status reports of the Delaware litigation to be submitted jointly every 75 days. The first report is due on **November 24, 2015**. The Clerk is requested to administratively close this case.

DATED: September 14, 2015

s/Mark Falk

MARK FALK
United States Magistrate Judge